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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,722	01/11/2002	Emanuel DiCicco-Bloom	270/175US	1548

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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,722	DICICCO-BLOOM ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *46-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's remarks filed 22 November 2004, in response to the restriction requirement of 28 October 2004, have been entered. Claims 1 – 45 have been cancelled and new claims 46 – 49 have been added. In the remarks of 22 November, Applicant indicates that the claims are believed to read on a single invention, rendering the restriction requirement moot. The examiner has considered the new claims fully, but believes that they still encompass multiple inventions. For instance, claims 46 and 47 are drawn to methods which comprise contacting cells with an agent. On p. 21 of the specification, "contacting" is defined to include both *in vitro* and *in vivo* methods. To the extent that claims 46 and 47 read on *in vitro* methods, they are patentably distinct from the methods of claims 48 and 49, which are limited to *in vivo* methods. Similarly, claim 47 is sufficiently broad as to encompass the use of either antisense nucleic acids or antibodies and both are contemplated on p. 4, paragraph [0012] of the specification. Methods using nucleic acids are considered gene therapy, are classified separately, and are examined by a separate art unit at the Office. Furthermore, claim 47 is sufficiently broad to include other compounds, for example small organic molecules. A new restriction requirement, detailing the patentably distinct inventions, follows.

Claim Objections

Claims 16 – 21 had been objected to by the examiner in the previous office action. Applicant has cancelled claims 16 – 21, therefore the objections are withdrawn.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 46, drawn to *in vitro* methods of modulating cell growth, classified in class 435, subclass 375.

II. Claims 46, drawn to *in vivo* methods of modulating cell growth, classified in class 514, subclass 12, for example.

III. Claim 47, drawn to methods of promoting proliferation of neuronal precursor cells by administering nucleic acids, classified in class 514, subclass 44.

IV. Claim 47, drawn to *in vitro* methods of promoting proliferation of neuronal precursor cells other than by administering nucleic acids, classified in class 424,

subclass 139.1, class 435, subclass 375, and class 514, subclass 12, for example.

V. Claim 47, drawn to *in vivo* methods of promoting proliferation of neuronal precursor cells other than by administering nucleic acids, classification dependent upon structure.

VI. Claims 48 and 49, drawn to methods of treating medical conditions caused by aberrant growth and increasing brain tissue by administering a PAC_1 ligand or antagonist thereby increasing cell growth or proliferation, classified in class 514, subclass 1, for example.

VII. Claim 48, drawn to methods of treating medical conditions caused by aberrant growth by administering a PAC_1 ligand, thereby decreasing cell growth or proliferation, classified in class 514, subclass 1, for example.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

Inventions I and IV are not related to inventions II, V, VI, and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions I and IV are to be performed *in vitro*, whereas the methods of Inventions II and V – VII are drawn to *in vivo* treatments. The *in vivo* methods necessarily require different starting materials than the *in vitro* methods; i.e. the former is to be practiced on subjects whereas the latter can be practiced on cultured cells.

Invention I is distinct and independent from Invention II because the two methods require different starting materials. The methods of Invention I are to be practiced *in vitro*, whereas the methods of Invention II are to be practiced *in vivo* on either human or non-human subjects. Therefore, the methods are patentably distinct and would require a separate search and consideration, presenting a burden for the office.

Invention I is distinct and independent from Invention IV because the two methods have different starting materials and goals. The goal of the method of Invention I is to modulate growth of neuronal precursor cells, whereas the goal of the method of Invention IV is to promote

proliferation of neuronal precursor cells. Cell growth is distinct from cell proliferation, so the goals of the methods are distinct. Invention I requires the use of a PAC_1 ligand, whereas Invention IV can use other compounds including, for example, forskolin (see Fukuchi et al., J Biol Chem 279:47856-47865). Therefore the methods of Invention I are patentably distinct from the methods of Invention IV, and would require a separate search and consideration.

Invention II is distinct and independent from Invention V because the methods require different starting materials. Invention II requires the use of a PAC_1 ligand. Invention V requires the use of a compound that decreases the expression of PACAP in a cell; as mentioned above this can include forskolin, which is not a PAC_1 ligand. Therefore the methods of Invention II are distinct and independent from the methods of Invention V, and would require a separate search and consideration.

Invention II is distinct and independent from both Inventions VI and VII, because the methods have different steps and goals. The methods of Invention II can be performed on subjects that are not in need of treatment, for example in the course of laboratory research. The methods of Inventions VI and VII, on the other hand, must be performed on subjects that either have a medical condition caused by aberrant growth of neuronal precursor cells, or "in need of treatment". Because the methods are to be performed on separate patient/subject populations, they would require separate search and considerations, presenting a burden for the office.

Invention III is distinct and independent from all other inventions. The method of Invention III requires the use of nucleic acids, which are not required as starting materials for any of the other methods. This is true whether the method is practiced *in vitro* or *in vivo*. Methods of gene therapy have acquired their own special status in the art, as indicated by their unique classification would necessitate a separate search and consideration, presenting a burden for the office.

Invention V is distinct and independent from Inventions VI and VII because the methods have different steps and goals. Invention VI requires the use of a PAC_1 ligand, which is not required for the methods of Invention V. The methods of Invention V can be performed on subjects that are not in need of treatment, for example in the course of laboratory research. The methods of Inventions VI and VII, on the other hand, must be performed on subjects that either have a medical condition caused by aberrant growth of neuronal precursor cells, or "in need of treatment". Because the methods are to be performed on separate patient/subject populations, they would require separate search and considerations, presenting a burden for the office.

Therefore Invention V is distinct and independent from Inventions VI and VII. Consideration of Invention V with either Invention VI or VII would require a separate search, presenting a burden for the office.

Inventions VI and VII are distinct and independent because they have different goals and are to be performed on separate patient populations. Both Inventions VI and VII require the use of a PAC_1 ligand, although Invention VI could also be accomplished with a PACAP antagonist, for example, an antibody. However, the methods of Invention VI are to be practiced on patients that are in need of increased cell growth (for example, patients with neurodegenerative diseases), whereas the methods of Invention VII are to be practiced on patients in need of decreased cell growth or inhibition of cell growth (for example, patients with cancer). Both increasing and decreasing cell proliferation by use of PAC_1 ligands are contemplated in the specification. Because the methods are to be practiced on separate patient populations, separate search of the literature would be required, presenting a burden for the office.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eileen B. O'Hara

EILEEN B. O'HARA
PATENT EXAMINER

Daniel E. Kolker, Ph.D.